K040615

JUN - 1 2004

510(k) Summary

Herbert J. Semler
1 March 2004

Trade name - CompressAR® SuperComfort™ Disc and StrongArm™ SuperComfort™ System
Common name - femoral access compression device
Classification name - Clamp, Vascular

This device is similar to the CompressAR® Universal System CompressAR® Comfort™ Disc, and is a modification of this predicate device. The CompressAR® SuperComfort™ Disc provides an elastomeric insert in the compression pad, and is used with a modified attachment to the CompressAR® StrongArm™ System to provide a two-step friction fit connection. The elastomer insert contacts the patient skin providing increased friction against the skin..

The CompressAR® SuperComfort™ Disc and StrongArm™ System is intended for use during and following femoral vascular catheterization procedures to assist in obtaining and maintaining hemostasis.

The disk and supporting stand provide a mechanical means of holding external pressure at or near the site of femoral vascular access. Direct pressure is used to obtain and maintain hemostasis, in a similar fashion to direct hand pressure on the access site or at a pressure point.

Testing was conducted to determine that the modified device provides mechanical clamping and holding functions, similar to the predicate device. It was concluded that the CompressAR® SuperComfort™ Disc and StrongArm™ System is equivalent to the predicate device.

2326 NW Everett St.
Portland, Oregon 97210
(503) 223-2333
(503) 223-8585 Fax
(800) 525-2555

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2004

Advanced Vascular Dynamics
c/o Herbert J. Semler, M.D.
Official Correspondent
2326 NW Everett Street
Portland, OR 97210

Re: K040615
CompressAR® SuperComfort™ Disc and StrongArm™ SuperComfort™ System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: May 14, 2004
Received: May 14, 2004

Dear Dr. Semler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040615

Device Name: CompressAR® Femoral Access Compression Device (SuperComfort)

Indications For Use:

This device is indicated for use to provide hemostasis of the femoral vascular access site during and following catheterization or cannulation procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lochner
(Division Sign-Off)
Division of Cardiovascular Devices

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